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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,645	02/10/2005	Claude Prigent	50376/004001	7358
21559	7590	07/07/2008	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			BRISTOL, LYNN ANNE	
			ART UNIT	PAPER NUMBER
			1643	
			NOTIFICATION DATE	DELIVERY MODE
			07/07/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/517,645	<b>Applicant(s)</b> PRIGENT ET AL.	
	<b>Examiner</b> LYNN BRISTOL	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2008 and 28 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-41 is/are pending in the application.
- 4a) Of the above claim(s) 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 26-41 are all the pending claims for this application.
2. Claims 1 and 14-25 were cancelled and new claims 26-41 were added in the Response of 3/28/08.
3. Claims 38-41 are withdrawn from examination as being drawn to subject matter corresponding to non-elected inventions by original presentation and set forth in the Office Action of 5/1/07.
4. The Declaration of Deposit by Dr. Prigent for the 35C1 hybridoma and filed with the Response of 1/17/08 is acknowledged and entered.
5. The examiner thanks Applicants' representative, Ms. Michaud, for the telephone interview of 6/26/08 in order to advance prosecution.
6. New Claims 26-37 are all the claims under examination and which correspond to the originally elected and examined claims of Group I (Claims 1, 14, 20 and 22). The species of cancer in new claim 33 are rejoined for examination.
7. Applicants amendments to the claims have necessitated new grounds for objection and rejection. This action is FINAL.

### **Withdrawal of Objections**

#### ***Specification***

8. The objection to the specification for being improperly arranged has been withdrawn in view of the amendments to the specification on pp. 2-5 of the Response of 3/28/08.

***Claim Objections***

9. The objections to Claims 1, 14 and 20 are withdrawn and moot for the cancelled claims.

**Withdrawal of Rejections**

***Claim Rejections - 35 USC § 112, second paragraph***

10. The rejection of Claims 1, 14, 20 and 22 for indefiniteness under 35 USC § 112, second paragraph, is withdrawn and moot for the cancelled claims.

***Claim Rejections - 35 USC § 112, first paragraph***

**Biological Deposit**

11. The rejection of Claim 14 under 35 U.S.C. § 112, first paragraph, in lacking enablement for the biological deposit for the hybridoma cell line 35C1 is withdrawn and moot for the cancelled claim.

***Priority***

12. The priority claim to PCT/FR03/01772 (filed 6/12/03) for the 35C1 monoclonal antibody is acknowledged. Applicants have provided a certified translation of the French language priority document, FR 02/07212 (filed 6/12/2002) in the Response of 1/17/08 to verify the priority for the claimed subject matter.

***Claim Rejections - 35 USC § 102***

13. The rejection of Claims 1, 14, 20 and 22 under 35 U.S.C. 102(a) as being anticipated by Cremet et al. (Molec. & Cell. Biochem. 243:123-131 (2003); cited in the IDS of 12/10/04) as evidenced by the HyCult Biotechnology datasheet for 35C1 (p. 1, 2/2004) is withdrawn and moot for the cancelled claims.

***Claim Rejections - 35 USC § 103***

14. The rejection of Claims 1, 20 and 22 under 35 U.S.C. 103(a) as being unpatentable over Honda et al. (Oncogene 19:2812-2819 (2000) as evidenced by Giet et al. (J. Cell Sci. 114: 2095-2104 (2001) and Shindo et al. (Biochem. Biophys. Res. Comm. 244:285-292 (1998)) in view of Bischoff et al. (Trends Cell Biol. 9:454-459 (1999) is withdrawn and moot for the cancelled claims.

**New Grounds for Objection**

***Claim Objections***

15. Claims 26-37 are objected to because of the following informalities: the recitation for the disclosed antigen, "aurora-A protein kinase" is recited inconsistently throughout the claims (e.g., aurora-A or aurora-A protein or aurora-A kinase).

Applicants agreed to the recitation "aurora-A protein kinase" in the telephone interview of 6/26/08.

16. Claim 31 is objected to for what appears to be a misunderstanding of the term "vector", and which should instead recite "vehicle" (see p. 4, line 28 of the specification for support).

Applicants agreed to the recitation "vehicle" in the telephone interview of 6/26/08.

Appropriate correction is required.

17. Claims 32-34 are objected to for reciting "a method for in vitro diagnostic or prognostic of cancers" when it would seemingly be more clear if claims 32 and 33 recited "diagnosis or prognosis" of cancers.

18. Claim 36 is objected to for omitting to include a comma after the term "respectively" in line 3.

Appropriate correction is required.

**New Grounds for Rejection**

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

19. Claims 26-37 are directed to an antibody. The claims read on any antibody or antibody fragment that is found in nature. Products of nature do not constitute patentable subject matter as defined in 35 USC 101. See MPEP 2105. Since an antibody does not exist in nature in purified form, it is suggested that Applicant use the language “isolated” or “purified” in connection with the antibody and antibody fragment to identify a product that is found in nature.

Applicants agreed to the recitation “An isolated 35C1 antibody” in Claim 26 in the telephone interview of 6/26/08.

20. Claims 32-34 are drawn to non-statutory subject matter. Claims 32-34 recite the “use” of the antibody in a method for diagnosing or prognosing cancers without reciting the method steps for performing the intended endpoint.

The claims could be amended to recite the method steps and to introduce subject matter that distinguishes the method from instant Claim 35. Alternatively, Claims 32-34 could be cancelled.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claims 27 and 32-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 27 recites the limitation "where aurora-A protein is secreted" in line 4.

There is insufficient antecedent basis for this limitation in the claim. The claims are directed to "human or murine" forms of the protein.

b) Claims 32-37 recite the limitation "a monoclonal antibody according to claim 26" in line 2 of Claim 32; line 3 of Claim 35; and line 3 of Claim 37. There is insufficient antecedent basis for this limitation in the claims. Claim 26 is drawn to the "35C1 antibody". Amending the claims to recite "said 35C1 monoclonal antibody" and deleting "a monoclonal antibody according to claim 26" would overcome the rejection. Further, kit claims 28-30 and the pharmaceutical composition claim 31 recite "said 35C1 antibody."

c) Claims 35-37 are indefinite for the recitation "if appropriate" in lines 4 and 5 of Claim 35 and in line 4 of Claim 37 because the phrase implies that different detection assay are intended within the scope, e.g., histology, western blotting, ELISA, etc., of the method but without actually being claimed. As for the kit of Claim 37, it is unclear whether or when the second marker is included. Is this optional? It would be clearer if Applicants introduced dependent claims supported by the specification for quantifying



assays (quantitative steps) and/or detecting assays (qualitative steps) for the protein to distinguish the different assays for in vitro diagnosis or prognosis.

d) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 35 recites the broad recitation "using marked reagents", and the claim also recites "in particular marked antibodies" which is the narrower statement of the range/limitation.

e) Claims 35-37 recites the limitation "in the complexes formed during the preceeding stage" in Claim 35. There is insufficient antecedent basis for this limitation in the claim.

f) Claims 35-37 are indefinite for the recitation "this, if necessary, after appropriate rinsing of the solid support" in the last line of claim 35 because it is not clear if the phrase "if necessary" means the step is optional in performed for the method

altogether, or whether in performing the method the ordinary artisan must determine whether or not to rinse.

g) Regarding claims 33, 34 and 37, the phrase "such as" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

h) Claim 36 is indefinite for the recitation "the determination of a quantity of aurora-A protein lower or greater than the normal physiological values in the biological sample" because the method in Claim 35 does not provide for obtaining a test sample and s a control sample, or using a control sample as a basis of comparison for a normal physiological value of the aurora-A protein kinase level. Thus the skilled artisan could not determine both the abnormal and normal physiological values for aurora-A protein kinase from the same biological sample.

i) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131

USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 37 recites the broad recitation “a marker of the PCNA protein”, and the claim also recites “in particular an anti-PCNA antibody” which is the narrower statement of the range/limitation.

### ***Conclusion***

22. No claims are allowed.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

/David J Blanchard/  
Primary Examiner, Art Unit 1643